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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,592	10/24/2001	Firdous Farooqui	2065-181	8167

22471 7590 02/18/2004

PATENT LEGAL DEPARTMENT/A-42-C  
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EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 02/18/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/032,592

Applicant(s)

FIRDOUS ET AL

Examiner

Mary (Molly) E. Ceperley

Art Unit

1641

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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**1)** The U.S. patents cited on form PTO-1449 filed January 31, 2002 have been considered.

Copies of the foreign patents and non-patent literature cited on these forms are not present in the file of this application and have not been considered. Upon receipt, the missing references will be considered when preparing the next Office action and a signed copy of form PTO-1449 will be provided to applicant with the next Office action.

**2)** The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code (see, for example, page 11, lines 25 and 26). See MPEP § 608.01.

**3)** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**4)** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**5)** Claims 1-74 are rejected under 35 U.S.C. 102(b)/103(a) as being anticipated by or obvious over Reddy et al (U.S. 5,648,213).

Reddy et al describe a method of producing an oligonucleotide-protein conjugate which includes the steps of **a)** reacting an oligonucleotide containing an amine group with a heterobifunctional reagent

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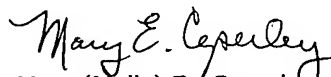
having a first reactive group (e.g. N-hydroxysuccinimide) specific for the amino groups of the oligonucleotide and a second reactive group (e.g. maleimide) specific for thiol groups of the protein moiety of the oligonucleotide-protein conjugate and **b)** reacting the thiol group of the protein with the thiol-reactive second reactive group of the heterobifunctionally derivatized oligonucleotide to form a oligonucleotide/protein conjugate. See Reddy et al: col. 5, lines 51-63; reaction scheme of col. 19; Example 1. The method and resulting product of Reddy et al anticipate the method of instant claim 1 and the product-by-process of instant claim 29. The ligand binding assay of instant claim 63 is anticipated by claim 22 of Reddy et al.

The features of the dependent claims are either specifically described by the references or constitute obvious variations in parameters which are routinely modified in the art (e.g. choice of well known equivalent analytes and heterobifunctional linkers) and which have not been described as critical to the practice of the invention. For example, for the use of a 5' NH<sub>2</sub> oligonucleotide (instant claim 5), see Reddy et al, col. 18, line 50; for the use of a sulfo-SMCC heterobifunctional linker (instant claim 12), see Reddy, col. 19, lines 18-25 (first line of the reaction scheme); for an immunoglobulin (protein) specific for a drug (instant claim 22), Reddy et al, Example 12; for well known equivalent heterobifunctional linkers (instant claim 12), see Reddy et al, col.6, line 8 – col. 7, line 13.

**6)** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823.

February 17, 2004

  
Mary (Molly) E. Ceperley  
Primary Examiner  
Art Unit 1641